

§ 25.56

material in question is generally recognized as a traditional ingredient in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor.”

(2) You may request a determination from TTB on whether or not the use of a process not listed in paragraph (a)(1) of this section will require the filing of a formula or whether the use of a particular coloring, flavoring or food material may be exempted from the formula filing requirement of paragraph (a)(3) or paragraph (a)(4) of this section. You should mail your request to the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(i) When requesting a determination as to whether a process is subject to the formula filing and approval requirement, the request must include:

(A) A detailed description of the proposed process;

(B) Evidence establishing that the proposed process is generally recognized as a traditional process in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor”; and

(C) An explanation of the effect of the proposed process on the production of a fermented product.

(ii) When requesting an exemption from the formula filing requirement in paragraph (a)(3) or paragraph (a)(4) of this section regarding coloring, flavoring, or food material ingredients, the request must include the following information:

(A) A description of the proposed ingredient;

(B) Evidence establishing that the proposed ingredient is generally recognized as a traditional ingredient in the production of a fermented beverage designated as “beer,” “ale,” “porter,” “stout,” “lager,” or “malt liquor”; and

(C) An explanation of the effect of the proposed ingredient in the production of a fermented product.

§ 25.56 Filing of formulas.

(a) *What are the general requirements for filing a formula?* (1) You must file your formula in writing. Your formula must identify each brewery where the

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formula applies by including each brewery name, address, and registry number.

(2) You must serially number each formula, commencing with “1” and continuing in numerical sequence.

(3) You must date and sign each formula.

(4) You must file two copies of each formula with TTB.

(b) *Where do I file a formula?* File your formula with the Assistant Chief, Advertising, Labeling and Formulation Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220.

(26 U.S.C. 5401, 7805)

§ 25.57 Formula information.

(a) *Ingredient information.* (1) For each formula you must list each separate ingredient and the specific quantity used, or a range of quantities used. You may include optional ingredients in a formula if they do not impact the labeling or identity of the finished product.

(2) For fermented products containing flavorings you must list for each formula: The name of the flavor; the product number or TTB drawback number and approval date of the flavor; the name and location (city and State) of the flavor manufacturer; the alcohol content of the flavor; and the point of production at which the flavor was added (that is, before, during, or after fermentation).

(3) For formulas that include the use of flavors and other nonbeverage ingredients containing alcohol, you must explicitly indicate:

(i) The volume and alcohol content of the beer base;

(ii) The maximum volumes of the flavors and other nonbeverage ingredients containing alcohol to be used;

(iii) The alcoholic strength of the flavors and other nonbeverage ingredients containing alcohol;

(iv) The overall alcohol contribution to the finished product provided by the addition of any flavors or other nonbeverage ingredients containing alcohol. You are not required to list the alcohol contribution of individual flavors and other nonbeverage ingredients containing alcohol. You may state the total alcohol contribution from these ingredients to the finished product; and

(v) The final volume and alcohol content of the finished product.

(b) *Process information.* For each formula you must describe in detail each process used to produce a fermented beverage.

(c) *Alcohol content.* For each formula you must state the alcohol content of the fermented product after fermentation and the alcohol content of the finished product.

(d) *Beer base formulas.* You must refer in your formula to any approved formula number that covers the production of any beer base used in producing the formula product. If the beer base was produced by another brewery of the same ownership, you must also provide the name and address or name and registry number of that brewery.

(e) *Additional information.* The appropriate TTB officer may at any time require you to file additional information concerning a fermented product, ingredients, or processes, in order to determine whether a formula should be approved or disapproved or whether the approval of a formula should be continued.

(26 U.S.C. 5415, 5555, 7805(a))

§ 25.58 New and superseding formulas.

(a) *New formulas.* Except as otherwise provided in paragraph (b) of this section, you must file a new formula (with a new formula number) for approval by TTB if you—

(1) Create an entirely new fermented product that requires a formula;

(2) Add new ingredients to an existing formulation;

(3) Delete ingredients from an existing formulation;

(4) Change the quantity of an ingredient used from the quantity or range of usage in an approved formula;

(5) Change an approved processing, filtration, or other special method of manufacture that requires the filing of a formula; or

(6) Change the contribution of alcohol from flavors or ingredients that contain alcohol.

(b) *Superseding formulas.* You may file a superseding formula, instead of a new formula, if you have made any change listed in paragraphs (a)(2) through (a)(6) of this section and that change is not of a type that would require a hold-

er of a certificate of label approval to file a new application for label approval on TTB Form 5100.31.

(1) A superseding formula replaces an existing formula, and you should file one only if you do not intend to use the existing formula any more. A superseding formula must be filed with TTB for approval. When TTB approves a superseding formula, TTB will cancel your previous formula.

(2) You may use the same formula number for a superseding formula that you used for the formula the superseding formula replaces, but you must annotate the formula number to indicate it is a superseding formula number. (For example, “Formula 2, superseding.”)

(c) When you file a new or superseding formula with TTB, you must follow the procedures and other requirements of §§ 25.56 and 25.57.

Subpart G—Qualification of a Brewery

ORIGINAL QUALIFICATION

§ 25.61 General requirements for notice.

(a) *Establishment.* Operations as a brewer may be conducted only by a person who has given notice as a brewer under this subpart. A person may not commence the business of a brewer until the appropriate TTB officer approves the brewery and the brewer's notice, including all documents made part of that notice.

(b) *Brewer's Notice, Form 5130.10.* Each person must, before commencing business as a brewer, give notice on Form 5130.10. Each person continuing business as a brewer as provided in § 25.71 must give notice on Form 5130.10. Each notice will be executed under penalties of perjury, and all written statements, affidavits, and other documents submitted in support of the notice will be made part of the notice.

(c) *Additional information.* The appropriate TTB officer may at any time require the brewer to furnish, as part of the notice, additional information